

## CLAIMS

1. A composition comprising Leukaemia Inhibitory Factor (LIF) or a derivative or homologue thereof and a stabilizing agent facilitating chemical and/or physical stability of LIF in the composition and one or more pharmaceutically acceptable carriers and/or diluents.
2. A composition according to claim 1 wherein the stabilizing agent facilitates reduced aggregation of LIF.
3. A composition according to claim 1 ~~or 2~~ wherein the stabilizing agent facilitates a reduction in the deamidation of LIF.
4. A composition according to claim 1 ~~or 2 or 3~~ wherein the pH of the composition is from between about 3.5 and 6.5.
5. A composition according to claim 3 wherein the pH of the composition is from between about 3.5 and 6.5.
6. A composition according to claim 1 ~~or 5~~ wherein the stabilizing agent is an isotonicity agent, an agent which increases or maintains the conformational stability of LIF or its derivatives or homologues or a surfactant or functional equivalents thereof.
7. A composition according to claim 6 wherein the stabilizing agent is an isotonicity agent selected from a polyhydric alcohol, a pharmaceutically acceptable salt, a buffer species, a sugar and a pharmaceutically acceptable polymeric compound.
8. A composition according to claim 7 wherein the polyhydric alcohol is sorbitol.

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9. A composition according to claim 6 wherein the surfactant is an anionic, cationic, amphoteric or non-ionic surfactant.
10. A composition according to claim 9 wherein the surfactant is selected from a fatty alcohol, a glyceryl ester and a fatty acid ester of a fatty alcohol or other alcohol.
11. A composition according to claim 6 wherein the stabilizing agent is selected from a polysorbate, a polyoxyethylene derivative and a pharmaceutically acceptable polyoxyethylene-polyoxypropylene copolymer.
12. A composition according to claim 7 wherein the buffer species is selected from a phosphate, citrate and acetate buffer.
13. A composition according to claim 12 wherein the buffer species is a citrate or acetate buffer.
14. A composition comprising Leukaemia Inhibitory Factor (LIF) and one or more pharmaceutically acceptable carriers and/or diluents and wherein the composition has a pH of between 3.5 and 6.5.
15. A composition according to claim 6 wherein the aggregation of LIF over time is reduced.
16. A composition according to claim 6 or 7 wherein the deamidation of LIF over time is reduced.
17. A composition according to claim 14 where the pH is maintained by the presence of a buffer species selection from a phosphate, citrate and acetate buffer.

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18. A composition according to claim 17 wherein the buffer species is a citrate or acetate buffer.

a 19. A composition according to claim 14, ~~17 or 18~~ wherein the pH is between from about 4.5 and about 5.5.

a 20. A composition according to claim 1 ~~or 14~~ wherein LIF is present in an amount from about 0.1 µg/ml to about 100 mg/ml.

Sub B4 21. A method for preparing a composition comprising Leukaemia Inhibitory Factor (LIF) or a derivative or homologue thereof and which exhibits reduced deamidation and/or agglutination of LIF or its derivative or homologues over time said method comprising admixing LIF or its derivative or homologue with a stabilizing agent.

22. A method according to claim 21 wherein the stabilizing agent is a isotonicity agent, an agent which increases or maintains the conformational stability of LIF or its derivatives or homologues or a surfactant or functional equivalents thereof.

23. A method according to claim 22 wherein the stabilizing agent is an isotonicity agent selected from a polyhydric alcohol, a pharmaceutically acceptable salt, a buffer species, a sugar and a pharmaceutically acceptable polymeric compound.

24. A method according to claim 23 wherein the polyhydric alcohol is sorbitol.

25. A method according to claim 22 wherein the surfactant is an anionic, cationic, amphoteric or non-ionic surfactant.

26. A method according to claim 25 wherein the surfactant is selected from a fatty alcohol, glyceryl ester and a fatty acid ester of a fatty alcohol or other alcohol.

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27. A method according to claim 22 wherein the stabilizing agent is selected from a polysorbate, a polyoxyethylene derivative and a pharmaceutically acceptable polyoxyethylene-polyoxypropylene copolymer.

Sub B5 28. A method according to claim 23 wherein the buffer species is selected from a phosphate, citrate and acetate buffer.

29. A method according to claim 28 wherein the buffer species is a citrate or acetate buffer.

30. A method according to <sup>claim 21</sup> ~~any of claims 22 to 29~~ further comprising adjusting the pH to between from about 3.5 and about 6.5.

31. A method according to ~~claim 30~~ wherein the pH is between from about 4.5 and about 5.5.

Sub B6 32. A method according to <sup>claim 21</sup> ~~any one of the claims 22 to 31~~ further comprising admixing one or more pharmaceutically acceptable carriers and/or diluents.

33. Use of a stabilizing agent in the manufacture of a composition exhibiting improved chemical and/or physical ~~stability~~ of Leukaemia Inhibitory Factor (LIF) or a derivative or homologue thereof.

Sub B7 34. Use according to claim 33 wherein the stabilizing agent is an isotonicity agent selected from a polyhydric alcohol, a pharmaceutically acceptable salt, a buffer species, a sugar and a pharmaceutically acceptable polymeric compound.

35. Use according to claim 34 wherein the polyhydric alcohol is sorbitol.

36. Use according to claim 34 wherein the surfactant is an anionic, cationic, amphoteric

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or non-ionic surfactant.

37. Use according to claim 36 wherein the surfactant is selected from a fatty alcohol, glyceryl ester and a fatty acid ester of a fatty alcohol or other alcohol.

38. Use according to claim 33 where the stabilizing agent is selected from a polysorbate, a polyoxyethylene derivative or a pharmaceutically acceptable polyoxyethylene-polyoxypropylene copolymer.

39. Use according to claim 34 wherein the buffer species is selected from a phosphate, citrate and acetate buffer.

40. Use according to claim 39 wherein the buffer species is a citrate or acetate buffer.

41. Use according to <sup>Claim 33</sup> ~~any one of claims 33 to 40~~ where the pH of the composition is between from about 3.5 to about 6.5.

42. Use according to <sup>Claim 41</sup> ~~any one of claims 41~~ wherein the pH is between from about 4.5 and about 5.5.